Innovita (Tangshan) Biological Technology Co., Ltd.
Address: No. 699 Juxin Street, High-tech Industrial Development Zone,Qian'an,064400,Hebei, China.
Phone: 86-10-83681277
Fax: 86-10-83682966
Website: www.innovita.com.cn

Clinical Test Report

Project Name (Code): 2019-nCoV Ab Test (Colloidal Gold)

Item Name (Code): Clinical Test Report

Project leader: Li Lanying

Participants: Zheng Chunlei, Chen Tingyou, Zhang Chunli, Xia Ruijuan

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Objective

To evaluate the quality performance and clinical application value of 2019-nCoV Ab Test (Colloidal Gold) produced by Innovita(Tangshan) Biological Technology Co., Ltd. The product passed the clinical assessment study of three hospitals.

Management of clinical assessment

Before the clinical assessment, the personnel of the R&D department of Innovita (Tangshan) Biological Technology Co., Ltd. and the technical director of the assessment unit (director of the department) will train the laboratory personnel. The training includes the purpose, operation method, and precautions of the clinical test, laboratory quality control standards and statistical analysis methods.

Clinical Evaluation Process

Sample collection and storage

Serum sample: Sample collection and storage according to clinical routine sterile venous blood collection was collected and distributed according to routine tests in the hospital. 2 ℃-8 ℃ and not more than 72 hours.

Test method

Comparison tests with test kit of the same type listed on the market

Innovita test kits were used, including “2019-nCoV Ab Test (Colloidal Gold)”, and the commercial PCR test which”performs simultaneous detection of all collected samples and reads the results within the specified time. After the test, the test results of the test kits were compared with the test results of the comparative test kits.

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Test Results

The clinical research unit confirmed 126 subjects, 110 samples were positive of assessment tests' antibody, sensitivity 87.3%; 62 subjects were excluded, 62 samples were negative of assessment tests' antibody, specificity 100%; The overall consistency was 91.49%.

There were 126 subjects with positive PCR products, 79 cases were positive of assessment tests, 16 cases were negative of assessment tests, 6 cases with IgM antibody positive and IgG antibody negative, 25 cases with IgM antibody negative and IgG antibody positive;

221 subjects with negative PCR products, 84 cases were positive of assessment tests, 100 cases were negative of assessment tests, 0 cases with IgM antibody positive and IgG antibody negative samples, 37 cases with IgM antibody negative, IgG antibody positive.

Conclusion

The clinical study test results of the 2019-nCoV Ab Test (Colloidal Gold) which developed by Innovita(Tangshan) Biological Technology Co., Ltd. show that the product has good sensitivity and specificity. The test process is suitable for clinical testing requirements. It has good consistency with the comparison test kits and can meet the basic clinical requirements.